

Drug Name: Palynziq (pegvaliase-pqpz)

Date: 4/15/19

| Drug Name: | Palynziq (pegvaliase-pqpz) |
|----------------|---|
| Required | Initial |
| Medical | Patient has a diagnosis of phenylketonuria (PKU) |
| Information: | Prescriber must be certified with Palynziq REMS program |
| | Patient currently uncontrolled on existing management and has a blood phenylalanine concentrations greater than 600 micromol/L. (labs to be provided) |
| | Patient has failed therapy with Kuvan. |
| | Patient must have prescription of auto-injectable epinephrine on hand at all times. |
| | • Patient has failed therapy with dietary restriction of phenylalanine. |
| | Renewal |
| | ● ≥20% reduction in blood phenylalanine concentration from baseline OR |
| | Blood phenylalanine concentration less than or equal to 600 micromol/L after 16 weeks of continuous treatment at max dose of 40 mg once daily |
| Quantity Limit | |
| Coverage | Initial: 20 weeks |
| duration: | Renewal: 1 year |